

K945518

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## EXHIBIT I

### 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

#### P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component - Smaller Sizes

Johnson & Johnson Professional, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767

#### 1. CONTACT PERSON

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#### 2. NAME OF DEVICE

Proprietary Name: P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component  
Common Name: Porous Coated Modular Femoral Prosthesis  
Classification Name: Hip Joint Metal/Polymer Semi-Constrained

#### 3. DEVICE CLASSIFICATION

Classification for porous coated modular femoral prosthesis has been placed in Class II by FDA (58 FR 3227, January 9, 1993).

#### 4. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component in the smaller sizes is substantially equivalent and identical in function to the P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component cleared for commercial distribution under premarket notification #K935452.

#### 5. INDICATIONS FOR USE

The P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component is indicated for use in total and partial hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of a prosthesis is also indicated for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, and disability due to previous fusion.

The P.F.C. 2 Total Hip System Porous Coated Modular Femoral Component is indicated for use without bone cement (PMMA).

#### 6. PHYSICAL DESCRIPTION

The P.F.C. 2 Total hip System Porous Coated Femoral Component in the smaller sizes is manufactured from titanium alloy (Ti-6Al-4V), the same material used to manufacture the P.F.C. 2 femoral components in the larger sizes. In addition to the sixteen sizes available under premarket notification #K935452, five additional sizes are available; three standard sizes (1/1, 2/2, and 3/3) and two additional sizes (2/1 and 3/2) to accommodate patient populations with proximal to distal incongruity.